K032458

OCT - 6 2003

510(k) Summary
Immunoassay/Clinical Chemistry Calibrators

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

Name of Submitter:
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Date of Preparation of 510(k) Summary: September 25, 2003

Trade Name(s):

Abbott ARCHITECT® Estradiol Calibrators
Abbott AxSYM® Estradiol Standard Calibrators
Abbott AxSYM® Estradiol Master Calibrators
Abbott ARCHITECT® FSH Calibrators
Abbott ARCHITECT® LH Calibrators
Abbott ARCHITECT® Progesterone Calibrators
Abbott ARCHITECT® Prolactin Calibrators
Abbott AxSYM® Total T3 Standard Calibrators
Abbott AxSYM® Total T3 Master Calibrators

Common Name: Abbott Immunoassay/Clinical Chemistry Calibrators

Device Classification: Class II

Classification Panel: Clinical Chemistry (75)

Product Code: JIT

Device Description:
Abbott Immunoassay/Clinical Chemistry Calibrators are devices intended for medical purposes for use in Abbott assay test systems to establish points of reference that are used in the quantitative determination of values in the measurement of substances in human specimens.

Conclusion:
Substantial equivalence is claimed to the legally marketed device as presented in the table below. In addition substantial equivalence has been demonstrated via the use of the FDA Guidance for Industry "Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators" issued on February 22, 1999,

Calibrator Name	Predicate Device	Similarities	Differences
ARCHITECT Estradiol Calibrators	IMx Estradiol Calibrators (K951629)	• Both are calibrators intended to establish points of reference. • Both are for use with quantitative immunoassays which detect Estradiol • Both are Tris Buffer based. • Both are standardized to an internal reference standards using Estradiol (purity no less than 97% by HPLC).	• IMx Estadiol Calibrators contain 6 levels (0, 50, 250, 750, 1500, 3000 pg/mL) intended to establish points of reference. • ARCHITECT Estradiol Calibrators contain 2 levels (0, 1600 pg/mL).
AxSYM Estradiol Standard Calibrators AxSYM Estradiol Master Calibrators	IMx Estradiol Calibrators (K951629)	• Both are calibrators intended to establish points of reference. • Both are for use with quantitative immunoassays which detect Estradiol • Both are Tris Buffer based. • Both contain 6 levels that are intended to establish points of reference.	• IMx Estradiol Calibrators are standardized to an internal reference standards using Estradiol (purity no less than 97% by HPLC). • AxSYM Estradiol Calibrators are standardized to an internal reference standard for AxSYM Estradiol. These internal standards are standardized to correlate with gas chromatography/mass spectrometry (GCMS). • IMx Estadiol Calibrators contain 6 levels at (0, 50, 250, 750, 1500, 3000 pg/mL) intended to establish points of reference. • AxSYM Estradiol Standard Calibrators contain 6 levels (0, 50, 100, 200, 500, 1000 pg/mL) intended to establish points of reference. • AxSYM Estradiol Master Calibrators contain 2 levels (0, 200 pg/mL) intended to establish points of reference.
ARCHITECT FSH Calibrators	Abbott FSH Calibrators (K890135)	• Both are calibrators intended to establish points of reference. • Both are for use with quantitative .immunoassays, which detect FSH. • Both are Bovine serum based. • Both sets of calibrators are manufactured by addition of Follicle Stimulating Hormone (FSH) of known concentration to obtain a target concentration. The concentration is referenced against World Health Organization (WHO) FSH 2nd International Reference Preparation (IRP) 78/549.	• ARCHITECT FSH Calibrators contain 2 levels (0, 100 mIU/mL) intended to establish points of reference. • Abbott FSH Calibrators contain 6 levels (0, 1, 10, 50, 100, 150 mIU/mL).
ARCHITECT LH Calibrators	AxSYM LH Standard Calibrators (K935611)	• Both are calibrators intended to establish points of reference. • Both are for use with quantitative immunoassays, which detect LH. • Both are calf serum based. • Both sets are of calibrators are manufactured gravimetrically and referenced to the World Health Organization (WHO) Luteinizing Hormone (LH) Human, Pituitary 2nd	• ARCHITECT LH Calibrators contain 2 levels (2, 100 mIU/mL) intended to establish points of reference. • AxSYM LH Calibrators contain 6 levels (0, 2, 10, 25, 100, 250 mIU/mL).

Calibrator Name	Predicate Device	Similarities	Differences
		International Standard 80/552 at each concentration.	
ARCHITECT Progesterone Calibrators	AxSYM Progesterone Standard Calibrators (K955025)	• Both are calibrators intended to establish points of reference. • Both are for use with quantitative immunoassays, which detect Progesterone.	• The ARCHITECT Progesterone Calibrators contain 2 levels (0.7, 40.0 ng/mL). • The AxSYM Progesterone Standard Calibrators contain 6 levels (0, 0.7, 2, 7, 20, 40 ng/mL). • The ARCHITECT Progesterone Calibrators are human serum based. • The AxSYM Progesterone Standard Calibrators are serum based for Level 0 and Tris buffer based for the remaining levels.
ARCHITECT Prolactin Calibrators	Abbott Prolactin Calibrators (K896162)	• Both are calibrators intended to establish points of reference. • Both are for use with quantitative immunoassays which detect Prolactin. • Both are referenced to the World Health Organization (WHO) 3rd International Standard 84/500 for Prolactin at each concentration level. • Both are Tris buffer based.	• The ARCHITECT Prolactin Calibrators contain 2 levels (5, 30 ng/mL). • The Abbott Prolactin Calibrators contain 6 levels (0, 5, 10, 30, 80, 200 ng/mL).
AxSYM Total T3 Standard Calibrators (LN 7A52-02) AxSYM Total T3 Master Calibrators (LN 7A52-32) which are Calibrators A and C of the Standard Calibrators	AxSYM Total T3 Standard Calibrators (K934517) AxSYM Total T3 Master Calibrators which are Calibrators A and C of the Standard Calibrators (K934517)	• Both are calibrators intended to establish points of reference. • Both are for use with quantitative immunoassays, which detect Total T3. • Both contain 6 levels (0, 0.5, 1, 2, 4, 8 ng/mL) for the Standard Calibrators and 2 levels (0, 1 ng/mL) for the Master Calibrators. • Both are bovine serum based.	• AxSYM Total T3 Standard Calibrators LN 7A52-02 and AxSYM Total T3 Master Calibrators 7A52-32 are manufactured using L-Triiodothyronine, sodium salt, (USP Grade) and signal matched to Abbott internal reference standards which are traceable to the USP Reference Standard L-Triiodothyronine (free acid) at each concentration level. The concentration of the T3 stock solution used to make the internal reference standards is determined by HPLC. • AxSYM Total T3 Standard Calibrators and AxSYM Totatl T3 Master Calibrators (K934517) are standardized as follows: Abbott manufactures internal reference standards for Total T3 using L-Triiodothryonine Sodium (HPLC purity 95.0-101.0%). Total T3 primary and secondary calibrators are manufactured gravimetrically utilizing this internal reference standard. All list material is tested against these primary and secondary calibrators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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OCT - 6 2003

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Re: k032458
Trade/Device Name: Abbott ARCHITECT® Estradiol Calibrators
Abbott AxSYM® Estradiol Standard Calibrators
Abbott AxSYM® Estradiol Master Calibrators
Abbott ARCHITECT® FSH Calibrators
Abbott ARCHITECT® LH Calibrators
Abbott ARCHITECT® Progesterone Calibrators
Abbott ARCHITECT® Prolactin Calibrators
Abbott AxSYM® Total T3 Standard Calibrators
Abbott AxSYM® Total T3 Master Calibrators

Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: September 15, 2003
Received: September 16, 2003

Dear Ms. Farmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

510(k) Number (if known):___K032458_____

Device Name: Abbott ARCHITECT® Estradiol Calibrators
Abbott AxSYM® Estradiol Standard Calibrators
Abbott AxSYM® Estradiol Master Calibrators
Abbott ARCHITECT® FSH Calibrators
Abbott ARCHITECT® LH Calibrators
Abbott ARCHITECT® Progesterone Calibrators
Abbott ARCHITECT® Prolactin Calibrators
Abbott AxSYM® Total T3 Standard Calibrators
Abbott AxSYM® Total T3 Master Calibrators

Indications For Use:

Abbott ARCHITECT Estradiol Calibrators are devices intended for use in the ARCHITECT Estradiol assay test system to establish points of reference that are used in the quantitative determination of estradiol in human specimens. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.

Abbott AxSYM Estradiol Standard Calibrators and AxSYM Estradiol Master Calibrators are devices intended for use in the AxSYM Estradiol assay test system to establish points of reference that are used in the quantitative determination of estradiol in human specimens. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.

Abbott ARCHITECT FSH Calibrators are devices intended for use in the ARCHITECT FSH assay test system to establish points of reference that are used in the quantitative determination of follicle-stimulating hormone (FSH) in human specimens. FSH measurements are used in the diagnosis and treatment of pituitary gland and gonadal discorders

ARCHITECT LH Calibrators are devices intended for use in the ARCHITECT LH assay test system to establish points of reference that are used in the quantitative determination of luteinizing hormone (LH) in human specimens. LH measurements are used in the diagnosis and treatment of gonadal function.

ARCHITECT Progesterone Calibrators are devices intended for use in the ARCHITECT Progesterone assay test system to establish points of reference that are used in the quantitative determination of progesterone in human specimens. Progesterone measurements are used in the diagnosis and treatment of disorders of the ovaries or placenta.

ARCHITECT Prolactin Calibrators are devices intended for use in the ARCHITECT Prolactin assay test system to establish points of reference that are used in the quantitative determination of prolactin in human specimens. Prolactin measurements are used in the diagnosis and treatment of disorders of the anterior pituitary gland or of the hypothalamus portion of the brain

AxSYM Total T3 Standard Calibrators and AxSYM Total T3 Master Calibrators are devices intended for use in the AxSYM Total T3 assay test system to establish points of reference that are used in the quantitative determination of total T3 in human specimens. Total T3 measurements are used in the diagnosis and treatment of thyroid disease.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use**
(Per 21 CFR 801.109)

Carol C. Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032458